Recall Procedures

A recall is a firm's voluntary removal of product from trade or consumer channels (e.g., by manufacturers, distributors, or importers) to protect the public from consuming adulterated or misbranded products. Recalls may be conducted on a firm's own initiative, by Food and Drug Administration (FDA) request or by FDA order under statutory authority, or by Food Safety and Inspection Service (FSIS) request in the case of meat and poultry products.

Recalls are divided into three classifications:

1. **Class 1-** A Class I recall involves a health hazard situation in which there is a reasonable probability that eating the food will cause health problems or death.
   Example: The presence of the bacteria *Listeria monocytogenes* in ready to eat meats and cheeses.
2. **Class II-** A Class II recall involves a potential health hazard situation in which there is a remote probability of adverse health consequences from eating the food.
   Example: The presence of an undeclared Class II allergen in a food product, such as MSG in the product without mention of the MSG on the label.
3. **Class III**- A Class III recall involves a situation in which eating the food will not cause adverse health consequences.
   Example: The addition of water to a processed meat without listing the water on the label as required by federal regulations.

Food product recalls in Missouri will follow the above classification system. Recalls initiated by Missouri firms voluntarily, or at the request of DHSS due to results of an epidemiologic investigation, consumer complaints, or routine sampling results, will be placed in one of the above categories based on the hazard level associated with the food.

When the food protection program in the Bureau of Environmental Regulation and Licensure (BERL) initiates or is officially notified of recalls announced by FDA or FSIS, the program will take appropriate action to prevent or limit exposure of consumers to the product in Missouri. Actions taken will include obtaining the name of the recalled product, size of containers, lot numbers involved, production dates, distribution sites in Missouri and neighboring states, adverse health effects caused by use of the product and disposition of product in distribution in Missouri. Notification of the local public health agencies will be through the use of the electronic fax system. A recall notification will include any distribution information provided by the recalling firm as well as any action that DHSS wants the local public health agency to take as a result of the recall.

The manufacturer or distributor may choose to issue a press release to announce the recall and/or call their customers directly prior to the issuance of or simultaneously with issue of the press release. There may be announcements regarding the recall on various "list-serves" on the Internet**. DHSS will not announce a recall until the announcement appears on the FDA or USDA website, or until it is received through official means of notification, via fax or electronic mail from either the FDA or USDA.**

Duties of BERL Staff:

1. Notify all local public health agencies, via Internet fax, of the occurrence of the recall and the desired action that the local public health agency should take in response to the recall, such as effectiveness checks.
2. Maintain ongoing communication with Regional Office staff and local public health agencies regarding recall status, and any changes in classification, additional products involved, etc.
3. Act as a liaison with federal and other state agencies; assist the FDA or FSIS in their ongoing investigation.
4. Notify Division Director's Office, Center for Local Public Health, BERL staff, and Bureau of Communicable Disease Control (BCDCP) staff of the recall.
5. Provide technical assistance to BERL and Local Public Health Agency staff.
6. Contact product distributors to determine the amount and presence of the recalled product in Missouri and assist in determining the extent of distribution of recalled product within Missouri.
7. Embargo recalled product, if necessary.
8. Assist the Office of Public Information and the Director's office in developing press releases.
9. Respond to consumer inquiries regarding the adverse health effects if a recalled product is consumed. *This information will be contained in the recall announcement itself or can be obtained from the local communicable disease coordinator.*
10. Serve on a recall team if assembled by the DHSS.

Common Responsibilities of LPHA

1. Follow the action that the DHSS Central Office Staff recommends in the recall notification announcement, such as checking retail outlets for presence of recalled product (effectiveness checks).
2. Respond to consumer inquiries regarding adverse health effects if the recalled product is consumed. This information will be contained in the recall announcement itself or can be obtained from the local communicable disease coordinator.
3. Place recalled product under embargo, if necessary.
4. Maintain communication with Central Office and Regional Office staff.

OTHER AGENCIES TO BE CONTACTED

U.S. Food & Drug Administration, Lenexa, Kansas
U.S.D.A. Food Safety & Inspection Service, Washington, D.C.

REFERENCE MATERIAL:

FDA Recall Policies Bulletin
Food Safety & Inspection Service Directive 8080